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TEXAS DEPARTMENT OF HEALTH

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Charles E. Bell, M.D.
Executive Deputy Commissioner

June 30, 2000

Ms. Margaret Dotzel
Acting Associate Commissioner for Policy
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm.1061
Rockville, MD 20852

Re: Department of Health and Human Services
Food and Drug Administration
21 CFR Part 900
Docket No. 99N-4578
RIN 0910-AB98
State Certification of Mammography Facilities

Dear Ms. Dotzel:

The Bureau of Radiation Control has reviewed the proposed §900, Mammography rules, and offers the following comments:

Supplementary Information

I. Background

(D) States as Certifiers Provisions

The first paragraph of (D) states that "§354(q) of the Public Health and Safety (PHS) Act allows FDA to delegate to qualified States, the authority for : (1) issuing, renewing, suspending, and revoking certificates, (2) conducting annual facility inspections and follow-up inspections, and (3) implementing and enforcing the MQSA quality standards for mammography facilities within the jurisdiction of the qualified state."

Comment: However, the third paragraph of (D) indicates that "FDA retains authority to suspend or revoke the certificate of facilities within an approved state." This is in conflict with the PHS Act. No reason is given for this decision. What if a state has been given that authority by state law?

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II. Provisions of the Proposed Rule
(D) Evaluation

Section 900.23 addresses the use of "performance indicators." This discussion states that FDA plans to provide further guidance on the nature of performance indicators and that the States as Certifiers (SAC) Demonstration Project is expected to be of significant value in developing this guidance.

Comment: Performance indicators should be delineated in the rule or developed as guidance and available for review and comment and not developed at a future date. Guidance on complying with these indicators could be developed at a later date, but the indicators themselves should be contained within the rule.

IV. Analysis of Impact

The inspection support fee of $509 will be billed by FDA to all non-governmental facilities within a state-certifying state for "inspection-related services that the agency has provided."

Comment: There is no indication as to what these services include and how the fee could be explained to our registrants. Does this fee include the following?

Initial training
Continuing education and travel for continuing education
Travel that is currently included under the contract
Annual evaluation of the certifying body

Section 900.21 Application for approval as a certification agency.
(a)(3)(iii)(F) This states that an applicant must submit to FDA the education, experience, and training requirements of the applicant's professional and supervisory staff.

Comment: The minimum criteria for education, experience, and training is not included in the rule. How would an applicant know if their staff was qualified?

Section 900.24 Withdrawal of approval.
First paragraph: "If FDA determines,...that a certification agency is not in substantial compliance, ..."

Comment: We suggest either defining "substantial compliance" or delete the word "substantial."

We appreciate the opportunity to comment on the proposed rules.

Sincerely,

Ruth E. McBurney for

Richard A. Ratliff, P.E., Chief
Bureau of Radiation Control

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